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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,170	05/19/2005	Nickolaos Robakis	5823GUS	5040
23911 7590 03/06/2008 CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300				
EXAMINER				
TELLER, ROY R				
ART UNIT		PAPER NUMBER		
1654				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/509,170

**Applicant(s)**

ROBAKIS ET AL.

**Examiner**

ROY TELLER

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 4-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-893)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 6/05

### **DETAILED ACTION**

Applicant's election without traverse of group I, claims 1-3 and 5-7; and the election of species, SEQ ID NO:1, which reads on claims 1-3, in the reply filed on 1/11/08 is acknowledged.

Claims 4-23 are withdrawn as being drawn to non-elected inventions.

Claims 1-3 are under examination, as they read on SEQ ID NO: 1.

### ***Information Disclosure Statement***

The information disclosure statement, received 6/3/05, is acknowledged. A signed copy is enclosed hereto.

### ***Objections***

The bib data sheet contains an incorrect priority date. The 60/372,617 priority document was received April 11, 2002. The bib data sheet incorrectly notes a priority date of October 5, 2001, drawn to 60/ 327, 617 (a retainer for a ball valve seat). Therefore, the correct priority date is April 11, 2002.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a “written description” rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

*Vas-Cath Inc. v. Mahurka*, 19 USPQ2d 1111, states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the “written description” inquiry, is *whatever is now claimed*” (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., the genus of a peptide comprising the sequence EGGGEEDQDFDL (SEQ ID NO: 1) wherein the peptide is from 5 to 15 amino acids in length, and a composition comprising the peptide.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43

USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states “An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention”.

There are species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* SEQ ID NO: 1, 4 and 5. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises the genus of a peptide comprising the sequence EGGGEEDQDFDL (SEQ ID NO: 1) wherein the peptide is from 5 to 15 amino acids in length, and a composition comprising the peptide, as the instant claims only identify SEQ ID NO: 5, a five amino acid peptide; SEQ ID NO: 4, a seven amino acid peptide; and SEQ ID NO: 1, a twelve amino acid peptide.

The written description requirement for a claimed genus may be satisfied through sufficient drawings, or by disclosure of relevant identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or

disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural or functional features, or critical conserved regions, of the genus and subgenera of proteins to be used in the claimed composition. There is not even identification of any particular portion of the structure that must be conserved. Structural features that could distinguish the proteins in the genus from others are missing from the disclosure. The specification and claims do not provide any description of what other changes should be made. There is no description of the other sites (other than those which applicant has possession of) at which variability may be tolerated and there is no information regarding the relation of structure to function. The general knowledge and level of those skilled in the art does not supplement the omitted description because specific, not general, guidance is what is needed. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed. Thus, no identifying characteristics or properties of the instant polypeptides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would not reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus or each subgenus.

The specification does not “clearly allow persons of skill in the art to recognize that [he or she] invented what is claimed” (see *Vas-Cath* at page 1116).

These definitions indicate that the term antagonist of a hedgehog polypeptide encompasses a large genus of variant proteins that are not limited to any particular sequence. Therefore, the claims encompass variants and fragments of antagonists of hedgehog proteins, in which one or more amino acids are substituted, deleted and/or inserted.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, first paragraph for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "...wherein the peptide is from 5 to 15 amino acids in length." This is vague and indefinite because it is unclear what the other 3 amino acids are, when SEQ ID NO: 1 (a 12 amino acid peptide) is the sequence. All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner et al. (USPN 6,787,136).

The instant invention is drawn to a peptide comprising the sequence EGGGEEDQDFDL (SEQ ID NO: 1) wherein the peptide is from 5 to 15 amino acids in length, and a composition comprising the peptide.

Brenner et al. beneficially discloses a peptide (fragment) - SEQ ID NO:3 (EEGGGEEDQD), an amino acid sequence of human E-cadherin residues 753-762 which reads on instant claims 1 and 2, in that the disclosed peptide is 10 amino acids in length and reads on instant SEQ ID NO: 4 (EGGGEED). See for example, column 55, sequence 3. Brenner further discloses a peptide - SEQ ID NO: 2, an amino acid sequence of human canherin-11 protein. Brenner beneficially discloses that a unique fragment of a cadherin-11 polypeptide will depend upon factors such as whether the fragment constitutes a portion of a conserved protein domain. Thus, some regions of SEQ ID NO: 2 will require only short segments, typically between 5 and 12 amino acids. Unique fragments of a polypeptide are those which retain a distinct functional capability of the polypeptide. SEQ ID NO: 2 contains the following fragment: <sup>666</sup>EGGGEED<sub>672</sub>, which is 7 amino acids in length and reads on instant claims 1-3 and SEQ ID NO: 4. See, for example, column 53, sequence 2, column 12; line 64- column 13, line 12.



It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the beneficial teachings of Brenner as a guide in preparing peptide fragments such as instantly claimed (as discussed above) because Brenner discloses that a unique fragment of a cadherin-11 polypeptide will depend upon factors such as whether the fragment constitutes a portion of a conserved protein domain. Thus, some regions of SEQ ID NO: 2 will require only short segments, typically between 5 and 12 amino acids. Unique fragments of a polypeptide are those which retain a distinct functional capability of the polypeptide.

From the teaching of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

### ***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Roy Teller/  
Examiner, Art Unit 1654  
2/27/08

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655